



U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

**INFORMATION DISCLOSURE
STATEMENT**

Docket Number:
1662/611055

Application Number
10/693,166

Filing Date
October 23, 2003

Examiner
To Be Assigned

Art Unit
To Be Assigned

Invention Title
POLYMORPHIC FORMS OF NATEGLINIDE

Inventor(s)
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P.O. Box 1450
Alexandria, VA 22313-1450

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450 on:

Date: July 14, 04 (52,048)
Signature: Payam Moradian

1. In accordance with the duty of disclosure under 37 C.F.R. § 1.56 and in conformance with the procedures of 37 C.F.R. §§ 1.97 and 1.98 and M.P.E.P. § 609, attorneys for Applicants hereby bring the following references to the attention of the Examiner. These references are listed on the attached modified PTO Form No. 1449. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom. The filing of this Information Disclosure Statement and the enclosed PTO Form No. 1449, shall not be construed as an admission that the information cited is prior art, or is considered to be material to patentability as defined in 37 C.F.R. § 1.56(b).
2. Copies of each patent, publication or other information listed on the modified PTO Form 1449 are not enclosed since they were previously cited by or submitted to the Patent Office in prior application Serial No. 10/622,905, filed July 18, 2003, which is relied upon for an earlier filing date under 35 U.S.C. 120. Please note disclosure of a purchase cited under "other documents."
3. Please note that reaction schemes of some of the foreign language art cited herein is provided in the background section of the invention.
4. It is believed that no fees are due in connection with this Information Disclosure Statement. However, should any fees be due the Commissioner is authorized to charge deposit account number 11-0600 for such fees. A copy of this communication is enclosed for charging purposes.

Dated: July 14, 04

By: Payam Moradian
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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT PTO-1449 | ATTY. DOCKET NO. 1662/611055 | SERIAL NO. 10/693,166 |
| | APPLICANT Ronit YAHALOMI et al. | |
| | FILING DATE October 23, 2003 | GROUP To Be Assigned |

U. S. PATENT DOCUMENTS

| EXAMINER INITIAL | PATENT NUMBER | PATENT DATE | NAME | CLASS | SUBCLASS | FILING DATE* |
|---------------------|------------------|-------------------|------------------|-------|----------|-----------------|
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FOREIGN PATENT DOCUMENTS

| EXAMINER INITIAL | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION | |
|---------------------|--------------------|--------------------|---------|-------|----------|-------------|----|
| | | | | | | YES | NO |
| | WO 01/21159 | March 29, 2001 | PCT | | | N/A | |
| | WO 02/32854 | April 25, 2002 | PCT | | | Abs. | |
| | WO 02/34254 | May 2, 2002 | PCT | | | Abs. | |
| | WO 02/34285 | May 2, 2002 | PCT | | | N/A | |
| | WO 02/34713 | May 2, 2002 | PCT | | | Abs. | |
| | WO 02/40010 | May 23, 2002 | PCT | | | Abs. | |
| | WO 03/022251 | March 20, 2003 | PCT | | | N/A | |
| | WO 03/076393 | September 18, 2003 | PCT | | | N/A | |
| | WO 03/087038 | October 23, 2003 | PCT | | | N/A | |
| | WO 03/087039 | October 23, 2003 | PCT | | | Abs. | |
| | WO 03/093222 | November 13, 2003 | PCT | | | N/A | |
| | 200200360 | July 2, 2002 | SK | | | Abs.* | |

* Application has not yet published; however, corresponding PCT application No. WO 01/21159 is enclosed.

OTHER DOCUMENTS

| EXAMINER INITIAL | | AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC. |
|---------------------|--|--|
| | | Hiroko Takesada et al., "Structure Determination of Metabolites Isolated from Urine and Bile after Administration of AY4166, a Novel D-Phenylalanine-Derivative Hypoglycemic Agent," Bioorganic & Medicinal Chemistry, Vol. 4, No. 10, 1996, pp. 1771-1781 |
| | | Hisashi Shinkai et al., "N-(Cyclohexylcartonyl)-D-phenylalanines and Related Compounds. A New Class of Oral Hypoglycemic Agents. 2," J. Med. Chem., Vol 32, 1989, pp. 1436-1441 |
| | | Xue-yan Zhu et al., "Study on Synthesis of Nateglinide," Hecheng Huaxue, Vol. 9, No. 6, 2001, pp. 537-540 |
| | | LI Gang et al., "A New Crystal Form of Nateglinide," Acta Pharmaceutica Sinica, Vol. 36, No. 7, 2001, pp. 532-534 |
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| | | A nateglinide having the enclosed XRD (see fig. 17) was purchased before July 3, 2002 in a foreign country from a supplier in another foreign country. |

| EXAMINER | DATE CONSIDERED |
|---|-----------------|
| EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | |